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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Display Date 12-18-03
Publication Date 12-19-03
Certifier A. Corbin

[Docket No. 2002D–0525]

Guidance for Industry and FDA Staff; Premarket Notification Submissions for Chemical Indicators; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled "Premarket Notification [510(k)] Submissions for Chemical Indicators." The document provides guidance for industry and other interested parties regarding the submission of chemical indicators such as process indicators, chemical integrators, and air removal indicators used in test packs.

DATES: Submit written or electronic comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies on a 3.5″ diskette of the guidance document entitled "Premarket Notification [510(k)] Submissions for Chemical Indicators" to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301–443–8818. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

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Submit written comments concerning this guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Chiu Lin, Center for Devices and Radiological Health (HFZ–480), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–443–8913, ext. 143.

SUPPLEMENTARY INFORMATION:

I. Background

This guidance is for chemical indicators intended for use in health care facilities. Chemical indicators are Class II devices identified in 21 CFR 880.2800. The chemical indicators discussed in the guidance document include process indicators, chemical integrators, and air removal indicators used in test packs such as the Bowie Dick Test Pack.

In the **Federal Register** of January 27, 2003 (68 FR 3887), FDA invited interested persons to comment by April 28, 2003, on the draft guidance entitled "Chemical Indicators Premarket Notification [510(k)] Submissions; Draft Guidance for Industry and FDA." FDA received one comment. FDA considered the comment and revised the guidance document for clarity.

II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices (GGPs) regulation (21 CFR 10.115). The guidance represents the agency's current thinking on chemical indicators used in health care facilities. It does not create or confer any rights for or on any person and does not operate

to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

III. Paperwork Reduction Act of 1995

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA) (44 USC 3501–3520). The collections of information addressed in the guidance document have been approved by OMB in accordance with the PRA under the regulations governing premarket notification submissions (21 CFR part 807, subpart E, OMB control number 0910–0120). The labeling provisions addressed in the guidance have been approved by OMB under OMB control number 0910–0485.

IV. Electronic Access

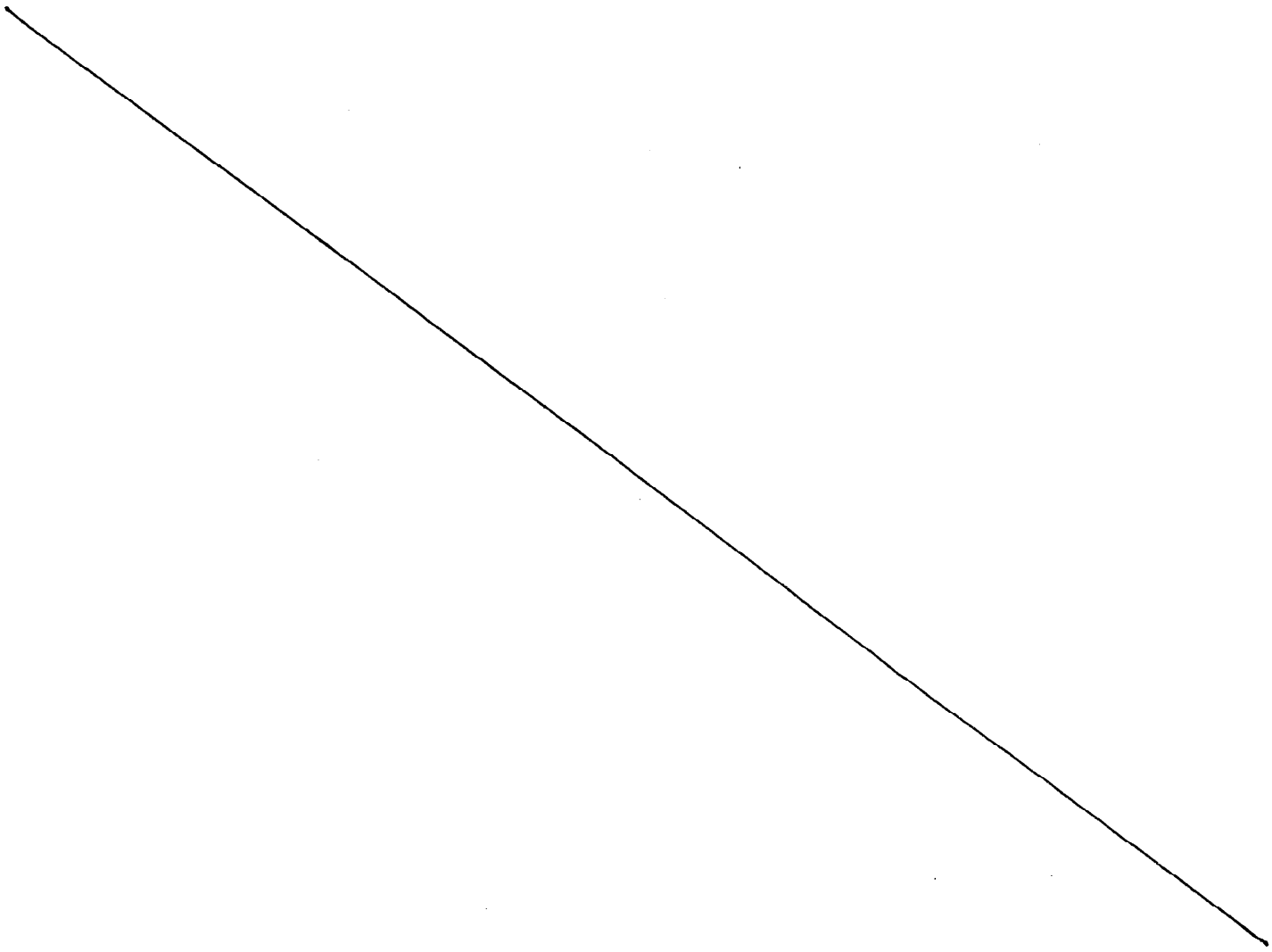
To receive a copy of "Premarket Notification [510(k)] Submissions for Chemical Indicators" by fax machine, call the Center for Devices and Radiological Health (CDRH) Facts-On-Demand system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. Press 1 to enter the system. At the second voice prompt, press 1 to order a document. Enter the document number (1420) followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the guidance may also do so by using the Internet. CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with Internet access. Updated on a regular basis, the CDRH home page includes device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturer's assistance, information on video conferencing and electronic submissions, Mammography

Matters, and other device-oriented information. The CDRH Web site may be accessed at *http://www.fda.gov/cdrh*. A search capability for all CDRH guidance documents is available at *http://www.fda.gov/cdrh/guidance.html*. Guidance documents are also available on the Division of Dockets Management Internet site at *http://www.fda.gov/ohrms/dockets*.

V. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**), written or electronic comments regarding the guidance at any time. Submit a single copy of electronic comments to *http://www.fda.gov/dockets/ecomments*, or submit two paper copies of any mailed comments, except that individuals may submit one copy. Comments are to be identified



with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: 12/4/03
December 4, 2003.

Linda S. Kahan,
Deputy Director,
Center for Devices and Radiological Health.

[FR Doc. 03–????? Filed ??–??–03; 8:45 am]

BILLING CODE 4160–01–S